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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,102	04/01/2004	Page W. Caufield	05986/100M320-US1	3947

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EXAMINER	
BAUSCH, SARAE L	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
08/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,102	CAUFIELD ET AL.	
	Examiner	Art Unit	
	Sarae Bausch PhD	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,20 and 44-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4, 20, 44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The after final amendment mailed 07/28/2009 has been entered. The finality of the last office action has been withdrawn. Any rejections or objections not reiterated in this action have been withdrawn. This office action presents new rejections and therefore is Non-Final. .

2. Currently, claims 4, 20, 44-46 are pending in the instant application. Claims 1-3, 5-19, 21-43 have been canceled. Claims 4, 20, 44-46 have been amended.

Claim Objections

3. Claim 43 is objected to because of the following informalities: claim 43 is not grammatically correct, claim 43 comprises a period after step (b) but does not have a period at the end of the claim. Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4, 20, 44-46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmaster et al. (Emerging Inf. Diseases, 2002, Vol 8, No. 10, supplement, p. 1-12) in view of German (Water Science and Technology, 2002, vol. 46, pp. 191-198), Manz (Microbiology, 1995, vol 141, pp 29-39), Eisenman (App Environ Microbio, 1998, vol 64, no 4, pp. 1264-1269) and Schlimme (Appl Environ Micro, 1999, pp. 254-2757)

Hoffmaster et al. teach evaluation and validation of RT-PCR for identification of Bacillus anthracis in environmental samples (See page 1, 2nd paragraph). Hoffmaster et al. teach elution of swab specimens and environmental samples in a aqueous solution (collection integrity is preserved) (see page 2, last paragraph cont'd to page 3). Hoffmaster et al. teach a wide variety of samples were tested including dust and vacuum cleaner debris (samples derived from street debris material, sample derived from a street sweeper machine, sample collected in predetermined traceable route) (sample from within a collection bin) (see Real-time PCR in environmental samples, page 5). Hoffmaster et al. teach testing environmental samples by PCR by elution of swab specimens and environmental samples in an aqueous solution (see page 2, last paragraph con't to page 3). Hoffmaster et al. teach testing the environmental specimens by real time PCR for the detection of B. anthracis (biological agent) (see real time PCR of environmental specimens, page 5). Hoffmaster et al. teach reporting the results of the PCR

analysis of the samples (see page 5 and page 7). Hoffmaster et al. teach testing the environmental sample by PCR and culture to determine the presence of B. anthracis. Hoffmaster teaches that 35 samples were positive by both methods and only 7 were positive by culture only, 4 positive by PCR only (see Real-time PCR in environmental samples, page 5 and page 7, last two paragraphs). Therefore, Hoffmaster, teaches assaying for the presence of a biological agent by comparing the level to a normal level in one or more routes (claim 12-14) (positive result in either PCR or culture). Hoffmaster teaches assaying for an increase or decrease relative to an earlier assay (claim 15-16) (PCR versus culture assay).

Hoffmaster does not teach materials are collected from a city street nor teach introducing tetrahymena pyriformis to the sample. Hoffmaster does not teach analysis of B. thuringiensis.

However, German teaches that there is a need to investigate the composition of street sweeping waste (see pg. 191). German teaches analysis of the composition of street sediment and street sweeping waste from a predefined collection route (see pg. 192 and figure 1).

Schlimme teaches Tetrahymena pyriformis can be used to detect bacterial toxicants and risk assessment of bacterial strains. Schlimme teaches determining the presence of multiple different bacterial strains, including two bacillus strains by adding bacteria to Tetrahymena (see pg. 2754, 2nd column). Schlimme teaches analysis of two different strains of B. cereus, B. thuringiensis, and E. coli. Schlimme teaches that E. coli was concentrated 10 to 100 fold within T. pyriformis and bacillus strains were not toxic to T. pyriformis. Thus Schlimme demonstrates the ability of T. pyriformis to concentrate and detect bacillus.

Eisenman demonstrates the ability of Tetrahymena to concentrate and detect bacteria in protozoa by hybridization. Eisenman teaches predation on bacteria attached to glass bead by

Tetrahymena sp. Eisenman teaches hybridization of ingested bacteria inside the food vacuoles of predators (see pg. 1264, 2nd column). Eisenman teaches densely packed bacteria within the food vacuoles of Tetrahymena (see pg. 1267). Thus Eisenman demonstrates the ability to detect and concentrate bacteria within Tetrahymena food vacuoles.

Manz demonstrates the ability of concentrating and determining the presence of biological agent by Tetrahymena. Manz et al. teaches analysis of environmental isolates to detect biological agent Legionella in Tetrahymena pyriformis (See abstract). Manz et al. teaches in situ hybridization of L. pneumophila within cells of T. pyriformis exposed to L. pneumophila (see pg. 31-32) and teaches that L. pneumophila is tightly packed within T. pyriformis (see pg. 36).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of evaluating the identification of Bacillus anthracis in environmental samples that included dust and vacuum cleaner debris as taught by Hoffmaster to include environmental samples from street sweeper debris collected from a street, as taught by German, to allow for analysis of the street sweeper waste obtain from a street. Additionally it would have been obvious to one of ordinary skill in the art to introduce Tetrahymena pyriformis to the street sweeper sample of Hoffmaster in view of German to detect bacillus anthracis, thurginesis or a bacillus spore in the sample as taught by Manz, Einsman, and Schlimme to allow for concentrating and detecting bacillus in an environmental isolate. The ordinary artisan would have been motivated to include street sweeper debris collected from the street as German teaches there is a need to investigate the composition of street sweeping waste from a city street and Hoffmaster teaches analysis of environmental samples to detect biological

agents. The ordinary artisan would have been motivated to add Tetrahymena pyriformis to detect bacillus spores in the street sweeper sample, including both anthracis and thurginesis strains because Eisenman demonstrates the ability of Tetrahymena to both concentrate and densely pack bacteria into food vacuoles, Manz demonstrates the ability to detect biological agent by Tetrahymena, and Schlimme demonstrates that bacteria is concentrated by Tetrahymena and demonstrates that neither bacillus spores tested are toxic to Tetrahymena, thus the ordinary artisan would have been motivated to use Tetrahymena to concentrate the bacteria present in the street sweeper sample, as was known in the art, followed by detection of the concentrated bacteria. The ordinary artisan would have had a reasonable expectation of success that an environmental sample that was obtained from a street collection site could be used in the method of Hoffmaster because Hoffmaster teaches analysis of different environmental samples, including dust and vacuum cleaner debris and German teaches a need to investigate the composition of street sweeping waste. Furthermore the ordinary artisan would have had a reasonable expectation of success that the addition of Tetrahymena to the environmental sample would allow for a more efficient analysis of bacillus spores, including anthracis and thuringiensis, in an environmental sample as the knowledge in the art demonstrates the ability of Tetrahymena to analyze bacteria samples in environmental samples as well as the ability of Tetrahymena to concentrate and detect bacteria within the food vacuoles, as taught by Manz, Eisenman, and Schlimme. Furthermore, the skilled artisan would have been motivated to test, detect, and concentrate additional strains and additional bacteria by the addition of T. pyriformis in environmental samples with a reasonable expectation of success as Manz, Eisenman, and Schlimme each demonstrate that Tetrahymena is capable of grazing on bacteria, specifically

bacillus spores, Tetrahymena concentrates and tightly packs bacteria inside the food vacuoles and demonstrates the ability to detect different bacteria within protozoa, such as by hybridization assay, therefore the skilled artisan would have been motivated to detect additional strains of bacillus with the expected predict results of Tetrahymena grazing and concentrating the bacteria within the environmental sample followed by detection of the bacteria.

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Sarae Bausch/
Primary Examiner, Art Unit 1634